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10/814,620	03/31/2004	Arthur O. Tzianabos	B0801.70280US01	5444

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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT	PAPER NUMBER
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1644

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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/814,620	Applicant(s) TZIANABOS ET AL.	
	Examiner Nora M. Rooney	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 17-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/21/2004 & 11/17/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-7 and 17-18 are pending.
2. Applicant's election without traverse of Group I, Claims 1-7 and 17-18 and the species of PSA1 in the reply filed on 02/21/2007 is acknowledged.
3. Claims 1-7 and 17-18 are currently under examination as they read on a method for treating an allergic condition other than asthma comprising administering PSA1 to a subject.
4. Applicant's IDS documents filed on 06/21/2004 and 11/17/2004 are acknowledged.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-7 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide enablement for a method for treating **an allergic condition other than asthma in a subject**, comprising: administering to a subject

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having an **allergic condition other than asthma** an isolated polymer in an effective amount to treat the allergic condition, wherein the polymer **comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate** of claim 1; wherein the motif is a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of phosphate, phosphonate, sulfate, and sulfonate of claim 2; wherein the administering comprises **delivering an aerosol of the polymer to an airway of the subject** of claim 3; wherein the subject is **free of symptoms otherwise calling for treatment with the polymer** of claim 4; wherein the polymer is a **polysaccharide** of claim 5; wherein the polymer is a **bacterial capsular polysaccharide** of claim 6; wherein the polymer is PSA1 of claim 7; wherein the method further comprises administering to **the subject** an anti-allergy medicament selected from the group consisting of glucocorticoids, antihistamines, and **anti-IgE** of claim 17; wherein the administering comprises administering to **the subject** having an **allergic condition other than asthma** multiple doses of the isolated polymer to treat **the allergic condition** of claim 18.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400,

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1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification on pages 52-54 in Example 5 discloses the proposed protocol for determining whether PSA can ameliorate asthma. On pages 55-56 in Example 8, the specification discloses the treatment procedure done on an allergic asthma model using Balb/c mice sensitized to OVA, injected with CP1 subcutaneously 3 times per week on days 1-27, boosted with OVA on day 21 and challenged with aerosolized OVA on days 28-29. The mice exhibited reduced OVA-specific IgE, deduced IL-13 and reduced eosinophil and goblet cell infiltration.

The specification does not disclose any examples of PSA1 being used to treat any allergic disease other than asthma in any patient. There is one example in the specification of CP1 being used to treat asthma in mice and there is one proposed experimental procedure in the specification for using PSA1 to treat asthma in mice. There is absolutely no support in the specification for a method of treating an allergic disease other than asthma. Allergic diseases other than asthma encompass allergic disease as diverse as food, drug, metal and pollen allergy. These allergic diseases have different responses, effect different people and have different etiologies. As evidenced by the specification on page 2, the zwitterionic polysaccharides of the present invention activate CD4+ T cells to produce the Th1 cytokines IL-2, IFN-gamma and IL-

10. However, skewing toward a Th1 response and producing IFN-gamma may not be therapeutic for all allergic diseases. For example, Hertl et al. (PTO-892, Reference U) teaches that data show that nickel allergic individuals have exhibited Th1, Th2 and Th0-type cells producing both Th1 and Th2 cytokines during the course of allergic disease (In particular, page 108, paragraph spanning left and right columns, whole document). In addition, Gonzalez-Hernández et al. (PTO-892, Reference V) teaches that although asthma is considered to be a Th2-biased immune response, that peripheral blood CD161+ T cells from asthmatic patients produce IFN-gamma, the hallmark Th1 cytokine, during acute asthma attacks (In particular, abstract, whole document). The art also shows that trying to alter the Th1/Th2 balance to treat allergy is not straight-forward. For example, Mamessier et al. (PTO-892, Reference W) teaches that targeting Th2 cytokines for allergic therapy has been disappointing because therapies which worked in animals did not work in humans or produced pro-inflammatory adverse events (In particular, 'Therapeutic implication' section pages 109-111). Therefore, the art is highly unpredictable as to what will be a therapy for any particular allergic disease, much less all allergic diseases in all patients. Given this unpredictability, it would require an undue amount of experimentation for one of ordinary skill in the art to practice the claimed invention commensurate in the scope with the claims which recite treating any allergic disease other than asthma in any patient.

The specification does not disclose adequate support for any isolated polymer which comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected

from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate. This recitation encompasses both molecules which have as yet been discovered and molecules which have been discovered which inherently possess these physiochemical properties. The recited polymer also encompasses peptides without disclosing the peptide sequences that would be encompassed by the claimed invention. Further, the description encompasses many species which would not work in the claimed invention. For example, Kalka-Moll et al. (IDS filed on 06/21/2004, Reference C21) teaches that the molecular size of the zwitterionic polysaccharides effects their ability to stimulate cellular immunity which is required for the claimed invention (In particular, title, abstract). The reference teaches that 22 repeating units of PSA are required to elicit a T cell dependent response. Therefore, since the recited polymer encompasses species that would not work in the claimed invention, known species with this undiscovered physiochemical characteristic and polymers species that are currently not known, practicing the method is highly unpredictable and it would require an undue amount of experimentation by one of ordinary skill in the art.

The term 'comprising' in claim 1 is open language which widens the scope of the claim to include polymer species that include additional molecules. As recited, the method for treating an allergic disease other than asthma could be the result of the interaction of the additional part(s) of the molecule and not due to the zwitterionic polymer portion at all. In addition, one of ordinary skill in the art would not know what can be added to the recited polymer that will not impact the ability of the polymer to treat allergic disease.

The examples in the specification for treating asthma include PSA1 and CP1. The specification does not disclose support for the terms 'polysaccharide' or 'capsular polysaccharide' in a method of treating an allergic condition other than asthma. Allergic disease treatment methods are unpredictable and there is no evidence provided in the specification that any polysaccharide or capsular polysaccharide with the recited motif would work. Cobb et al. (PTO-892, Reference X) teaches that until recently it was thought that the MHCII pathway to present antigen to T cells strictly utilized protein antigens. However, the zwitterionic capsular polysaccharide unexpectedly also follows this classical path of presentation. The reference also teaches that very little is known about how these molecules work. Therefore, there is a great degree of unpredictability in the art as to how these polymers work and whether or not all zwitterionic polysaccharides or capsular polysaccharides would work in the claimed invention.

The recitation of a patient who is free of symptoms otherwise calling for treatment with the polymer is also not enabled. As discussed *supra* very little is known about these polymers and what they can treat, so how would you define a symptom that calls for treatment with the polymer.

The term 'anti-IgE' is not enabled. The term encompasses any molecule whose action opposes that of any IgE with any specificity. There is no support in the specification for all such molecules.

Finally, the recitation of administering comprises delivering an aerosol to of the polymer

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to an airway of the subject is not enabled. The specification provides one example of a polymer reduced to practice in treating asthma and it is by administering the polymer injected i.p..

Considering that the claims are directed to all allergic diseases other than asthma, it is highly unpredictable that administration of the polymer to the airway of the subject will treat all allergic diseases, including contact dermatitis and food allergy. It would require an undue amount of experimentation by one of ordinary skill in the art to determine what allergic diseases will be treated by an aerosol delivery mode of administration other than asthma or another respiratory disease.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

7. Claims 1-7 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of treating asthma in a mouse by injecting the mouse with isolated PSA1.

Applicant is not in possession of: a method for treating **an allergic condition other than asthma** in a **subject**, comprising: administering to a **subject** having **an allergic condition other than asthma** an **isolated polymer** in an effective amount to treat the allergic condition, wherein the polymer **comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA)**, the motif being a **positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate** of claim 1; wherein the motif is a **positively charged free amino moiety and a negatively charged moiety selected from the group consisting of phosphate, phosphonate, sulfate, and sulfonate** of claim 2; wherein the administering comprises delivering an aerosol of the polymer to an airway of the subject of claim 3; wherein the subject is **free of symptoms otherwise calling for treatment with the polymer** of claim 4; wherein the polymer is a **polysaccharide** of claim 5; wherein the polymer is a **bacterial capsular polysaccharide** of claim 6; wherein the polymer is **PSA1** of claim 7; wherein the method further comprises administering to **the subject** an anti-allergy medicament selected from the group consisting of glucocorticoids, antihistamines, and **anti-IgE** of claim 17; wherein the administering comprises administering to **the subject** having **an allergic condition other than asthma** multiple doses of the **isolated polymer** to treat **the allergic condition** of claim 18.

The specification on pages 52-54 in Example 5 discloses the proposed protocol for determining whether PSA can ameliorate asthma. On pages 55-56 in Example 8, the specification discloses the treatment procedure done on an allergic asthma model using Balb/c mice sensitized to OVA, injected with CP1 subcutaneously 3 times per week on days 1-27, boosted with OVA on day 21 and challenged with aerosolized OVA on days 28-29. The mice

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exhibited reduced OVA-specific IgE, deduced IL-13 and reduced eosinophil and goblet cell infiltration.

The specification does not adequately describe any examples of PSA1 being used to treat any allergic disease other than asthma in any patient. There is one example in the specification of CP1 being used to treat asthma in mice and there is one proposed experimental procedure in the specification for using PSA1 to treat asthma in mice.

The specification does not adequately describe any isolated polymer which comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate. This recitation encompasses both molecules which have as yet been discovered and molecules which have been discovered which inherently possess these physiochemical properties. The recited polymer also encompasses peptides without disclosing the peptide sequences that would be encompassed by the claimed invention.

The term 'comprising' in claim 1 is open language which widens the scope of the claim to include polymer species that include additional molecules. The specification does not adequately describe a method for treating an allergic disease other than asthma that could be the result of the interaction of the additional part(s) of the molecule and not due to the zwitterionic polymer portion at all. In addition, one of ordinary skill in the art would not know what can be added to the recited polymer that will not impact the ability of the polymer to treat allergic

disease.

The examples in the specification for treating asthma include PSA1 and CP1. The specification does not adequately describe the terms 'polysaccharide' or 'capsular polysaccharide' in a method of treating an allergic condition other than asthma.

The recitation of a patient who is free of symptoms otherwise calling for treatment with the polymer is also not adequately described. As discussed *supra* very little is known about these polymers and what they can treat, so how would you define a symptom that calls for treatment with the polymer.

The term 'anti-IgE' is not adequately described. The term encompasses any molecule whose action opposes that of any IgE with any specificity. There is no support in the specification for all such molecules.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and

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structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-2, 4-6, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 03/075953 (IDS filed on 06/21/2004, Reference B3) as evidenced by the specification in original claim 10, now canceled.

The WO 03/075953 reference teaches a method for treating an allergic condition other than asthma (eczema, acute respiratory distress syndrome) in a subject, comprising: administering to a subject having an allergic condition other than asthma (eczema, acute respiratory distress syndrome) an isolated polymer in an effective amount to treat the allergic condition, wherein the polymer comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate (In particular, claims 18 and 21, page 7, lines 5-12); wherein the motif is a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of phosphate, phosphonate, sulfate, and sulfonate (In particular, claims

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18 and 21, page 7, lines 5-12); wherein the subject is free of symptoms otherwise calling for treatment with the polymer; wherein the polymer is a polysaccharide (CP1); wherein the polymer is a bacterial capsular polysaccharide (CP1); wherein the administering comprises administering to the subject having an allergic condition other than asthma (eczema, acute respiratory distress syndrome) multiple doses of the isolated polymer to treat the allergic condition (In particular, page 28, lines 1-3).

Claims 1-2, 4-6 and 18 are included in this rejection because original claim 10, now canceled, is dependent from current original claim 1. Therefore, CP1 has all of the characteristics recited in claims 1-2, and 5-6.

The reference teachings anticipate the claimed invention.

10. Claims 1-2, 4-6, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0119164 (PTO-892, Reference A) as evidenced by the specification in original claim 10, now canceled.

The US 2005/0119164 reference teaches a method for treating an allergic condition other than asthma (eczema, acute respiratory distress syndrome) in a subject (In particular, claim 21, paragraph [0026]), comprising: administering to a subject having an allergic condition other than asthma an isolated polymer (CP1) in an effective amount to treat the allergic condition (eczema, acute respiratory distress syndrome), wherein the polymer (CP1) comprises repeating units of a

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charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate; wherein the motif is a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of phosphate, phosphonate, sulfate, and sulfonate (CP1); wherein the subject is free of symptoms otherwise calling for treatment with the polymer; wherein the polymer is a polysaccharide (CP1) (In particular, claim 21, paragraph [0026]); wherein the polymer is a bacterial capsular polysaccharide (CP1) (In particular, claim 21, paragraph [0026]); wherein the administering comprises administering to the subject having an allergic condition other than asthma multiple doses of the isolated polymer to treat the allergic condition (In particular, paragraph [0111]).

Claims 1-2, 4-6 and 18 are included in this rejection because original claim 10, now canceled, is dependent from current original claim 1. Therefore, CP1 has all of the characteristics recited in claims 1-2, and 5-6.

The reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

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11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/59515 (IDS filed on 06/21/2004) in view of Tang et al. (PTO-892, Page 2, Reference U).

WO 00/59515 teaches a method for treating a Th1 cell responsive disorder in a subject, comprising: administering to a subject having a Th1 cell responsive disorder an isolated polymer in an effective amount to treat the allergic condition, wherein the polymer comprises repeating units of a charge motif characteristic of B. fragilis polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate (In particular, page 14, lines 9-17, page 32, lines 3-13); wherein the motif is a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of phosphate, phosphonate, sulfate, and sulfonate (PS A); wherein the subject is free of symptoms otherwise calling for treatment with the polymer; wherein the polymer is a polysaccharide (PS A); wherein the polymer is a bacterial capsular polysaccharide (PS A); wherein the polymer is PSA1 (PS A); wherein the administering comprises administering to the subject having a Th1 cell responsive disorder multiple doses of the isolated polymer to treat the allergic condition (In particular, page 27, line 16).

Claim 7 is included in this rejection because the specification on page 42, lines 21-23 disclose that PSA1 is also called PSA.

The reference teachings differ from the prior art by the recitation of treating an allergic disease other than asthma and wherein the administering comprises delivering an aerosol of the polymer to an airway of the subject.

Tang et al. teaches that allergic inflammation is a Th2-mediated disease. The reference also teaches that an immune switch to Th1 can protect against Th2-mediated allergic responses (In particular, abstract, whole document). In addition, Tang teaches that Th1 stimulating activity of lung macrophages is responsible for the inhibition of allergic airway inflammation (In particular, title, abstract) and that nasal injection into the lungs of the mice was the preferred route for targeting the inflammatory reaction in the lung (In particular, page 1472, 'Lung Cell Transfer' and 'Immunization and Airway Challenge' sections).

It would have been obvious to one of ordinary skill in the art to apply the method of treating an Th1 cell responsive disorder of the WO 00/59515 reference to treat the allergic airway inflammation of Tang et al. because Tang et al. teaches that an immune switch from a Th2 response to a Th1 response can protect against allergic airway inflammation. It would also have been obvious to deliver the polymer by aerosol in order to target the cells in the lung with the polymer to treat the allergic airway inflammation by skewing the Th2 response to a Th1

response in the local environment of the lung. Claim 3 is also included in this rejection because it would be conventional and within the preview of those skilled in the art to identify and determine the administering route to treat an allergic condition. Further, since the allergic condition includes acute respiratory distress syndrome characterized by airway inflammation, pulmonary administration would be the target. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claims 1-7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,026,285 (PTO-892, Reference B) in view of Tang et al. (PTO-892, Page 2, Reference Y).

The '285 patent teaches a method for treating a Th1 cell responsive disorder in a subject, comprising: administering to a subject having a Th1 cell responsive disorder an isolated polymer in an effective amount to treat the allergic condition, wherein the polymer comprises repeating

units of a charge motif characteristic of *B. fragilis* polysaccharide A (PSA), the motif being a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of carboxyl, phosphate, phosphonate, sulfate, and sulfonate (In particular, column 11, line 13-25 and column 24, lines 35-51); wherein the motif is a positively charged free amino moiety and a negatively charged moiety selected from the group consisting of phosphate, phosphonate, sulfate, and sulfonate (PS A); wherein the subject is free of symptoms otherwise calling for treatment with the polymer; wherein the polymer is a polysaccharide (PS A); wherein the polymer is a bacterial capsular polysaccharide (PS A); wherein the polymer is PSA1 (PS A); wherein the administering comprises administering to the subject having a Th1 cell responsive disorder multiple doses of the isolated polymer to treat the allergic condition (In particular, column 20, lines 65-66).

Claim 7 is included in this rejection because the specification on page 42, lines 21-23 disclose that PSA1 is also called PSA.

The reference teachings differ from the prior art by the recitation of treating an allergic disease other than asthma and wherein the administering comprises delivering an aerosol of the polymer to an airway of the subject.

Tang et al. teaches that allergic inflammation is a Th2-mediated disease. The reference also teaches that an immune switch to Th1 can protect against Th2-mediated allergic responses (In particular, abstract, whole document). In addition, Tang teaches that Th1 stimulating activity of lung macrophages is responsible for the inhibition of allergic airway inflammation (In particular, title, abstract) and that nasal injection into the lungs of the mice was the preferred

route for targeting the inflammatory reaction in the lung (In particular, page 1472, 'Lung Cell Transfer' and 'Immunization and Airway Challenge' sections).

It would have been obvious to one of ordinary skill in the art to apply the method of treating an Th1 cell responsive disorder of the '285 patent to treat the allergic airway inflammation of Tang et al. because Tang et al. teaches that an immune switch from a Th2 response to a Th1 response can protect against allergic airway inflammation. It would also have been obvious to deliver the polymer by aerosol in order to target the cells in the lung with the polymer to treat the allergic airway inflammation by skewing the Th2 response to a Th1 response in the local environment of the lung. Claim 3 is also included in this rejection because it would be conventional and within the preview of those skilled in the art to identify and determine the administering route to treat an allergic condition. Further, since the allergic condition includes acute respiratory distress syndrome characterized by airway inflammation, pulmonary administration would be the target. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over 2005/0119164 (PTO-892, Reference A) as evidence by the specification in view of Thomas et al. (PTO-892, Page 2, Reference V).

The 2005/0119164 reference has been discussed *supra*.

The reference teachings differ from the prior art by the recitation of wherein the method further comprises administering to the subject an anti-allergy medicament selected from the group consisting of glucocorticoids (corticosteroids) and anti-IgE.

Thomas et al teaches administering corticosteroid to patients with eczema to reduce itching and other symptoms (In particular, abstract, whole document).

It would have been obvious to one of ordinary skill in the art to apply the method of administering glucocorticoids to treat eczema of Thomas et al. to the method for treating an allergic condition other than asthma in a subject including eczema in the US 2005/0119164 reference (In particular, claim 21, paragraph [0026]) because Thomas et al. teaches that glucocorticoids reduce itching associated with eczema (In particular, whole document). It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually

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taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 13, 2007

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